

**PSJ2 Exh 171**

**File Provided Natively**

# Pain Franchise 2012 PR Program

February 10, 2012



## 2012 Brand and Communications Environment

- Acute market mostly generic; chronic pain market less so
- Media coverage heavily weighted towards abuse/misuse/diversion
  - Opioids covered as a class, not by brand
- Plight of pain patients under-reported, but tide is starting to turn
- Tighter restrictions on MDs, NPs, PAs and pharmacists
  - Places burden on prescribing and dispensing
- NUCYNTA® and NUCYNTA® ER have low brand awareness; media coverage tied to data/regulatory milestones

***Must differentiate NUCYNTA® / NUCYNTA® ER with media in a meaningful way to separate them from the pack, illustrating a need in the market and positioning the product as a potential solution***

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### **Key takeaways:**

- 1) Must identify and maximize appropriate data and regulatory opportunities with media and
- 2) Must create additional ways to differentiate and distinguish NUCYNTA IR/ER for media

## Key PR Insight: The NUCYNTA® / NUCYNTA® ER Difference Could Be a Solution

- **Environment polarized by two critical yet interconnected issues**
  - Meeting the needs of pain patients
  - Epidemic of opioid abuse, misuse and diversion
- **PR hypothesis and new potential narrative:**  
NUCYNTA® / NUCYNTA® ER may be able to help on both fronts
  - High incidence of GI side effects with opioids (constipation, nausea, vomiting)
    - Some patients abandon therapy, leaving them without efficacy and relief
    - Unused pills in the medicine cabinet can lead to diversion
  - Studies show that NUCYNTA® and NUCYNTA® ER have proven efficacy, a favorable tolerability profile, and favorable discontinuation rates

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**Janssen R&D conducting company head-to-head study  
between NUCYNTA® ER and Oxycontin to confirm.**

## Long-Term PR Intent...

***Build out this narrative and deliver data points that establish NUCYNTA® and NUCYNTA® ER as the right choice for patients and a potential solution to a broader societal problem.***

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**NUCYNTA® & NUCYNTA® ER  
2012 Marketing Strategies**

**Strategic Imperatives**

**VISION: NUCYNTA® & NUCYNTA® ER redefine pain management success**

**Establish NUCYNTA® & NUCYNTA® ER as new standard in moderate-severe pain mgt.**

**Drive broad and competitive access and availability**

**Demonstrate industry leadership in advocacy for HCP & patient access**

**Strengthen differentiation & value through new & compelling evidence**

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**Strategic Assignment for 2012 PR Business Plan:**  
**Raise Brand Visibility, Differentiate the Brand with Media,**  
**Educate/Influence to Maintain Physician/Patient Access**

**HEALTH AFFAIRS**  
Targeted public affairs programs designed to educate and influence key stakeholders (policy makers, media, HCPs) to help maintain access to NUCYNTA® and NUCYNTA®ER

**THE HILL**  
**POLITICO**

**RELIEF INTERRUPTED**  
A multi-pronged initiative that highlights low discontinuation rates for opioid therapy as an important unmet medical need and a potential solution to a dual challenge

**PAIN MEDICINE NEWS**  
**The Star-Ledger**  
**Internal Medicine News**  
**CNN**  
**The Wall Street Journal**  
**Dispatch**  
**The Washington Post**

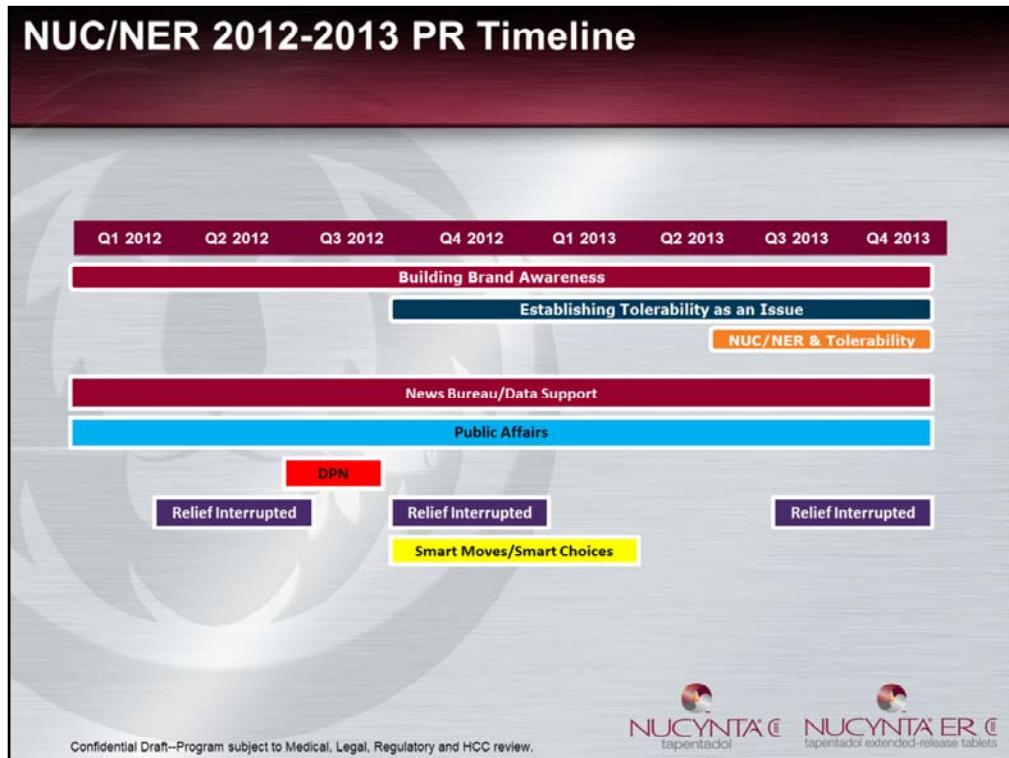
An ongoing NUCYNTA®/NUCYNTA®ER news bureau where creative story ideas are pursued over a 24-month period in concert with campaigns that educate and correct inaccuracies

**Smart Moves Smart Choices**

Support for the FDA approval of the DPN indication, positioning NUCYNTA® ER as solution and the only opioid option available to this under-treated population

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H2H study data reporting timing to be added

Smart Moves program elements to be verified, moved to appropriate timing areas

## Raising Brand Visibility/Awareness and Differentiation: News Bureau

- **Rationale**
  - Ongoing NUCYNTA® and NUCYNTA® ER news bureau
  - Allows for a steady drumbeat of brand visibility in the media
  - Scalable based on budget
  - Expands media focus beyond abuse/diversion
    - Re-focus on patient needs

**PAIN MEDICINE NEWS** **CNN**  
**The Star-Ledger** **The Columbus Dispatch**  
**Internal Medicine News** **The Washington Post**

An ongoing NUCYNTA®/NUCYNTA®ER news bureau where creative story ideas are pursued over a 24-month period in concert with campaigns that educate and correct inaccuracies

24 MONTHS OF CREATIVE STORYTELLING THAT SUPPORT NUCYNTA/NUCYNTA ER											
JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER
New York Times Opinion piece: "The Real Story About Tapentadol"	APRIL: Creative media event NOT ER	A March to the End: Tapentadol (not ER) is the real story about pain management	The creation of new identity of pain management and its evolution. Showcasing the evolution of pain treatment	Spring 2012: Stories, Tapentadol and the future of pain management. Showcasing the evolution of pain treatment	Summer 2012: Stories, Tapentadol and the future of pain management. Showcasing the evolution of pain treatment	Autumn 2012: Stories, Tapentadol and the future of pain management. Showcasing the evolution of pain treatment	Tapentadol: The year in pain relief	Tapentadol: The year in pain relief	Tapentadol: The year in pain relief	Tapentadol: The year in pain relief	Tapentadol: The year in pain relief
APRIL CDC's Disease Prevention and Health Protection: The Safe Prescription of Tapentadol for Chronic Pain	MAY FDA: Tapentadol: Disease Awareness Month	JUNE Tapentadol: Disease Awareness Month	JULY Informational piece: Tapentadol and the future of pain management	AUGUST Tapentadol: The year in pain relief	SEPTEMBER Tapentadol: The year in pain relief	OCTOBER Tapentadol: The year in pain relief	NOVEMBER Tapentadol: The year in pain relief	DECEMBER Tapentadol: The year in pain relief			
OCTOBER Informational piece: Tapentadol: The Safe Treatment of Chronic Pain	NOVEMBER Marketing campaign from: DPA Approved	DECEMBER Informational piece: Tapentadol: The year in pain relief									

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## Media Relations – NUCYNTA® / NUCYNTA® ER Message Track

- *New England Journal of Medicine* editorial (Jan. 2012) from Dean of Stanford Med School quotes IOM study
  - More than 116 million Americans have chronic pain
  - Financial costs ranging from \$560 to \$635 billion per year
- Many patients lack access to effective, tolerable pain meds; others discontinue due to side effects or lack of efficacy
- Patients respond differently, and doctors and patients need options
- NUCYNTA® / NUCYNTA® ER are options with
  - Proven efficacy and safety in moderate to severe pain models
  - Favorable tolerability profile
  - Favorable discontinuation rates

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“The magnitude of pain in the United States is astounding,” write the authors of a January 2012 *New England Journal of Medicine* article which found that more than 116 million Americans have pain that persists for weeks to years with associated financial costs ranging from \$560 billions to \$635 billion per year.

Many of these patients lack access to effective, tolerable pain medication while others are treated but discontinue due to side effects or lack of efficacy.

Clearly, doctors and patients need options so patients can find relief.

NUCYNTA® IR/ER has demonstrated proven efficacy and safety in moderate to severe pain models.

NUCYNTA® IR/ER has a favorable tolerability profile and favorable discontinuation rates.

## Seizing Near-Term Media Opportunities: News Bureau Q1-Q2, 2012

### February

- **HCP Media Pitch:** Reporter briefings @ AAPM
  - News Hook: Posters on new data
    - NUCYNTA® v. Oxy IR in lower back pain with radicular leg pain
    - HECOR: Physician piece of P3 survey
    - Two RADARS posters:
      - Non-med use of tapentadol: The first 18 months
      - Non-med use of opioids/tapentadol among college students
- **Mainstream Media Pitch:** "Women are feeling the pain, study says--what every woman needs to know"
  - News Hook: Gender difference study in *Journal of Pain*

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NUCYNTA v. Oxy IR poster—Non-inferiority, plus better GI tolerability for NUCYNTA

## Seizing Near-Term Media Opportunities: News Bureau Q1-Q2, 2012

### March

- **HCP Media Pitch:** Veterans--tools for dealing with chronic pain
  - News Hook: Those who have served, need to be served
- **Mainstream Media Pitch:** "The long road home"--Iraq/Afghanistan troops the next gen of chronic pain patients
  - News Hook: Major troop withdrawals, return to civilian life with chronic pain

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NUCYNTA v. Oxy IR poster—Non-inferiority, plus better GI tolerability for NUCYNTA

## Seizing Near-Term Media Opportunities: News Bureau Q1-Q2, 2012

### April

- **Mainstream Media Pitch:** "When Work Hurts: Occupation and workplace pain"
  - News Hook: Tailored to workforce in priority markets, focusing on repetitive stress injuries, accidents and impact of chronic pain

### May

- **HCP Media Pitch:** Pr. release timed to Amer Pain Society (16<sup>th</sup>-19<sup>th</sup>)
  - News Hook: Poster on new data—2<sup>nd</sup> DPN Study (prior to August PDUFA)
- **Mainstream Media Pitch:** "Bouncing back from surgery"--Movement after total knee/hip is vital to recovery
  - News Hook: Data supports need to be ambulatory after surgery; ineffective pain management can limit mobility and contribute to health decline

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"When Work Hurts: Occupation and workplace pain" (public servants, construction, athletes, skilled labor)

## Seizing Near-Term Media Opportunities: News Bureau Q1-Q2, 2012

### June

- **HCP Media Pitch:** Patient survey shows impact of discontinuation on pain management and diversion
  - News Hook: New survey reveals potential for opioid abuse and diversion
- **Mainstream Media Pitch:** Patient survey shows impact of discontinuation on pain management and diversion
  - News Hook: New survey reveals potential for opioid abuse/diversion; how physicians can help address the problem

### Late 2012

- **HCP Media Pitch:** Press release timed to publication
  - News Hook: New data--Extension of NUCYNTA® ER 1-Year Safety Study

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NUCYNTA v. Oxy IR poster—Non-inferiority, plus better GI tolerability for NUCYNTA

## Building Blocks to Engage Media

- Refine NUCYNTA® / NUCYNTA® ER story track; mine opportunities
- Leverage clinical / HECOR data, medical meeting presentations as available and appropriate
- Opportunistic events
- Patient stories (as we can find them)
- Chronic pain media briefing
- Reporter's/writer's guide on chronic pain

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- **Chronic pain media briefing—May be most appropriate for when there's new data to share or before the DPN indication PDUFA/Approval. Maybe to cover**
  - chronic pain,
  - DPN,
  - neuropathic pain, or
  - role of an opioid in treating neuropathic pain
- **Writer's guide can be teed up for DPN so we can highlight MOA**

## Raising Brand Visibility/Awareness and Differentiation: FDA Action on sNDA for DPN

### • Rationale

- Capitalizes on news event in high-interest disease area (diabetes)
- Provides platform to highlight and differentiate NUCYNTA® ER
  - Difficulty of treating neuropathic pain drives message of efficacy
- Program is scalable
  - Support for FDA approval only
  - Abbreviated science writer's guide
  - Focus on business/medical trade media



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## FDA Action on sNDA for DPN

- Prepare scenario plan
- Develop/implement:
  - Media strategy
  - Media materials
  - Spokespeople



Support for the FDA approval of the DPN indication, positioning NUCYNTA® ER as solution and the only opioid option available to this under-treated population

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# RELIEF INTERRUPTED

*A multi-pronged, multi-year initiative that highlights favorable tolerability and discontinuation rate as a key differentiator for NUCYNTA® and NUCYNTA® ER and a potential solution to a dual challenge*

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A multi-pronged, multi-year initiative that **highlights favorable tolerability a discontinuation rate as a key differentiator for NUCYNTA® and NUCYNTA® ER** and a potential solution to a dual challenge

Helps differentiate in the earned media space; fills in the gaps between data opportunities

## Differentiate the Brand with Media: Relief Interrupted

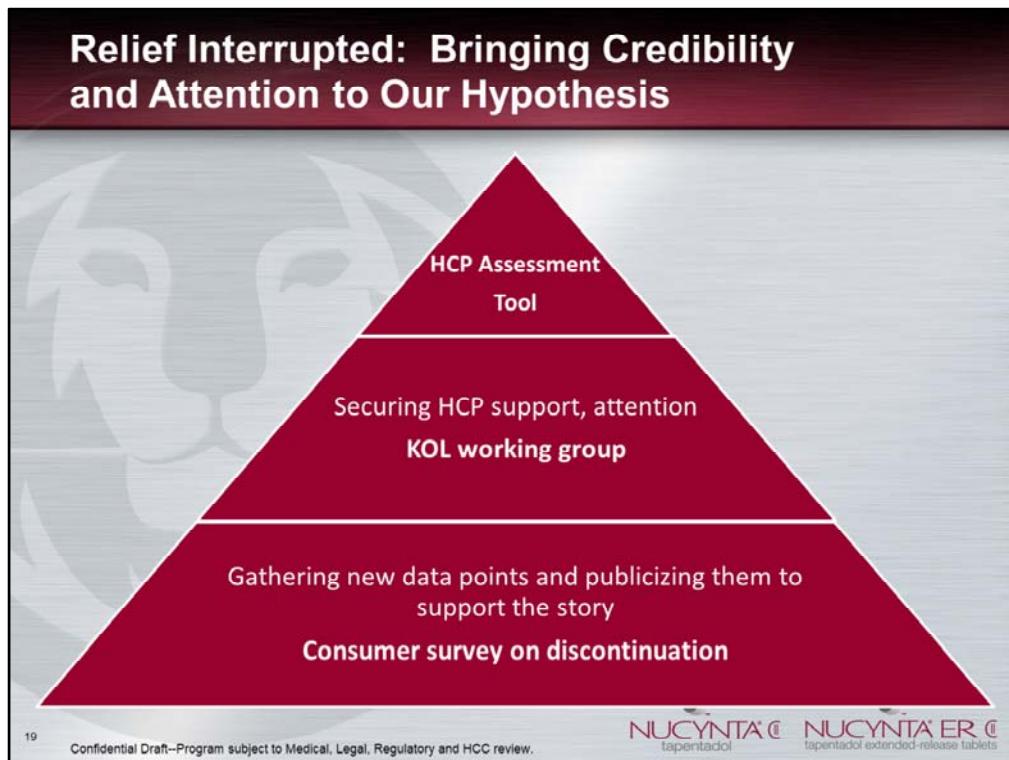
- **Rationale**
  - Tolerability and discontinuation are real issue for many patients on LAO therapy
  - Points to a dual problem
    - sub-optimal pain management
    - potential for abuse/diversion
  - Focus on discontinuation data
  - Program is scalable
    - Execute some elements in 2012 and the rest in 2013
  - Multiple media relations touch points



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A multi-pronged initiative that **highlights the low discontinuation rate as a key differentiator for NUCYNTA** and a potential solution to a dual challenge



This graphic shows the building blocks for Relief Interrupted and what they allow us to do.

- Survey will link tolerability and discontinuation, pinpoint when patients go off therapy, what they take for pain instead of opioids, how often if at all they speak to their doctor about it and how many unused pills are leftover – ripe for abuse and diversion.
- The KOL working group adds credibility and “buzz” to the effort and allows us to build a program “designed by doctors for doctors.” **At the end of the day, the goal here is to change physician prescribing behavior –get them to stop and think before they write.**
- All this ladders up to the creation of an assessment tool that will allow doctors to identify patients at risk of going off opioid and offer them a different solution with a favorable tolerability profile with the same efficacy as what they were taking.
- Another point to make: this program was conceived with the goal of maximizing earned media throughout the process:
  - Media opp #1: Survey results
  - Media opp #2: White paper dissemination
  - Media opp #3: Start of real world clinical study of assessment tool
  - **Media opp #4: Publication of clinical study results in peer-reviewed journal**
  - Media opp #5: Launch of tool

## Educate/Influence to Maintain Physician and Patient Access: Public Affairs/Policy Support

### • Rationale

- Laser-focus on states where access is threatened
- Cost-effective way to reach critical stakeholders
- Direct channel to deliver content (Relief Interrupted, DPN indication)
- Supports HCPs
- Offers Janssen, NUCYNTA® / NUCYNTA® ER "a seat at the table"
- Enables media coverage opportunities in Beltway, policy/payer outlets, key states



Targeted public affairs programs designed to educate and influence key stakeholders (policy makers, media, HCPs) to help maintain access to NUCYNTA® and NUCYNTA® ER

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## Elements of Public Affairs/Policy Support

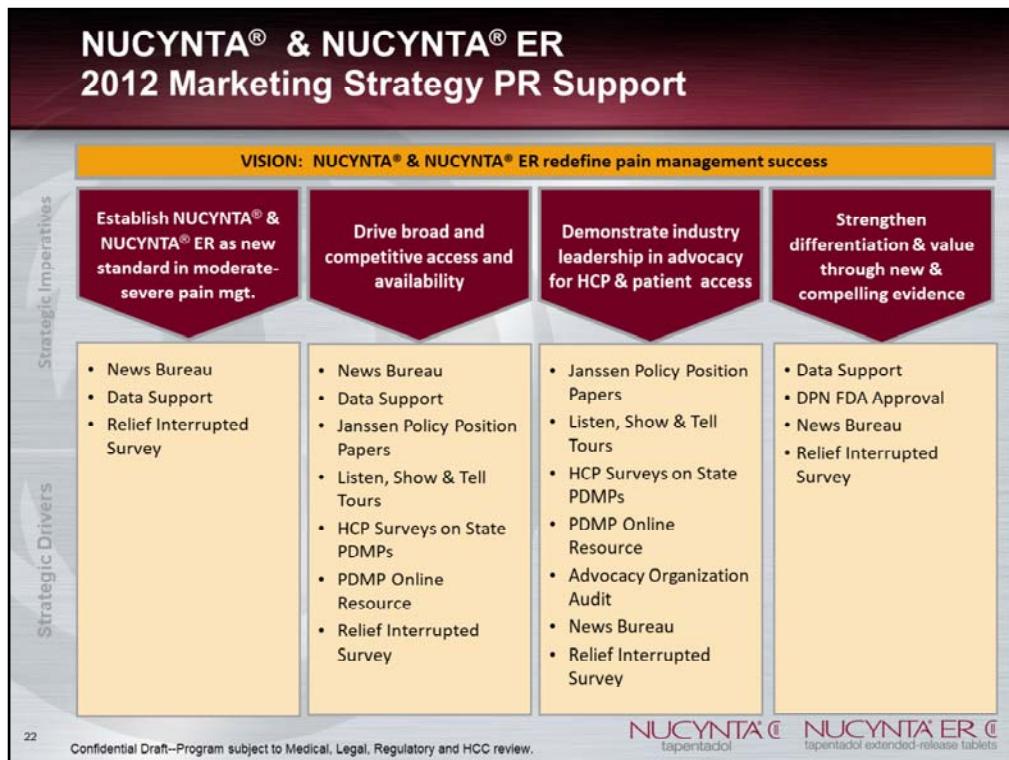
- **Janssen Policy Position Statements**
  - Conveys Janssen POV on legislation, other issues
- **Prescription Drug Monitoring Program (PDMP) online resource**
  - Extension of state seminars to educate physicians on PDMPs
- **HCP PDMP Survey (national, state, medical meetings)**
  - Quantify impact of PDMPs on HCPs' pain prescribing/patient care; show Janssen is listening
- **Listen, Show and Tell tours**
  - Help state and federal policymakers better understand the "balancing act" of regulating opioids
- **Advocacy Audit**
  - Assess pain advocacy landscape and make partner recommendations based on communication and organization ROI

State PDMP Awareness

Congressional Caucus Listening Tour

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## Educate/Influence to Maintain Physician and Patient Access: *Smart Moves, Smart Choices*

- Continue/expand use of School Tool Kit
  - Field survey of Tool Kit recipients to find out usage/implementation in middle and high schools
  - Explore partner options for impacting implementation of programs in schools
- “Family Matters” public service campaign
  - Rationale: Where families are engaged, teen Rx drug abuse is lower
  - Target audiences: Parents, grandparents
  - Booklet, new web pages, video series



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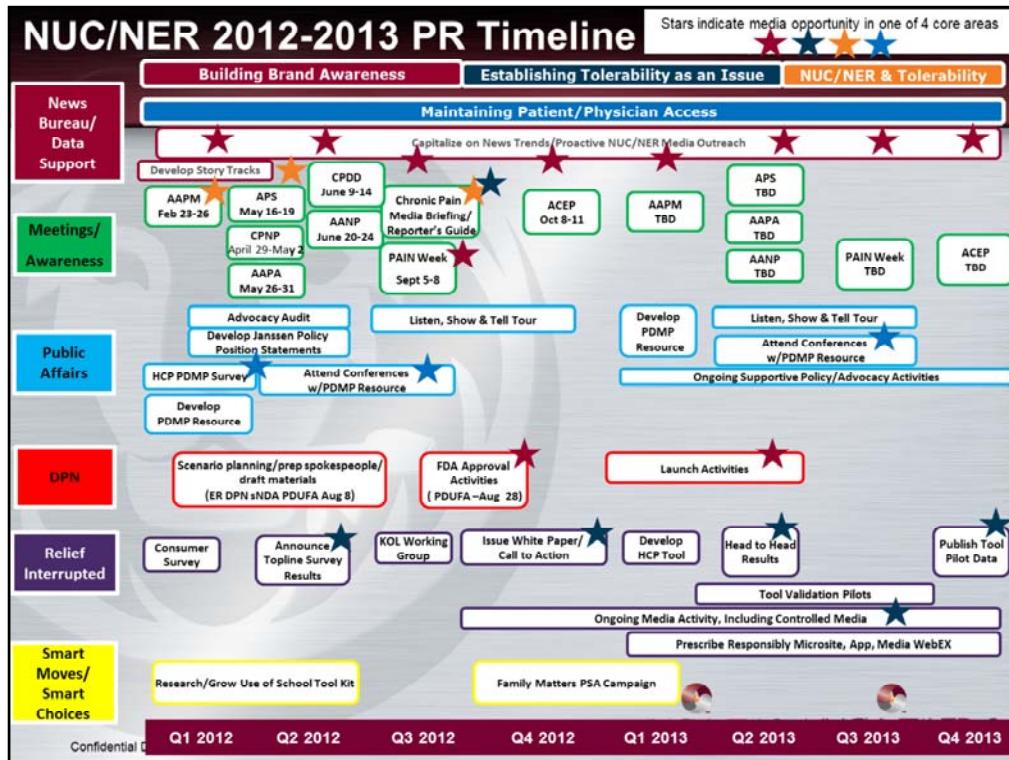
### Teen video shorts

Develop funny, engaging or amusing videos and leverage online for “viral” intent

### School Learning Tool for elementary students

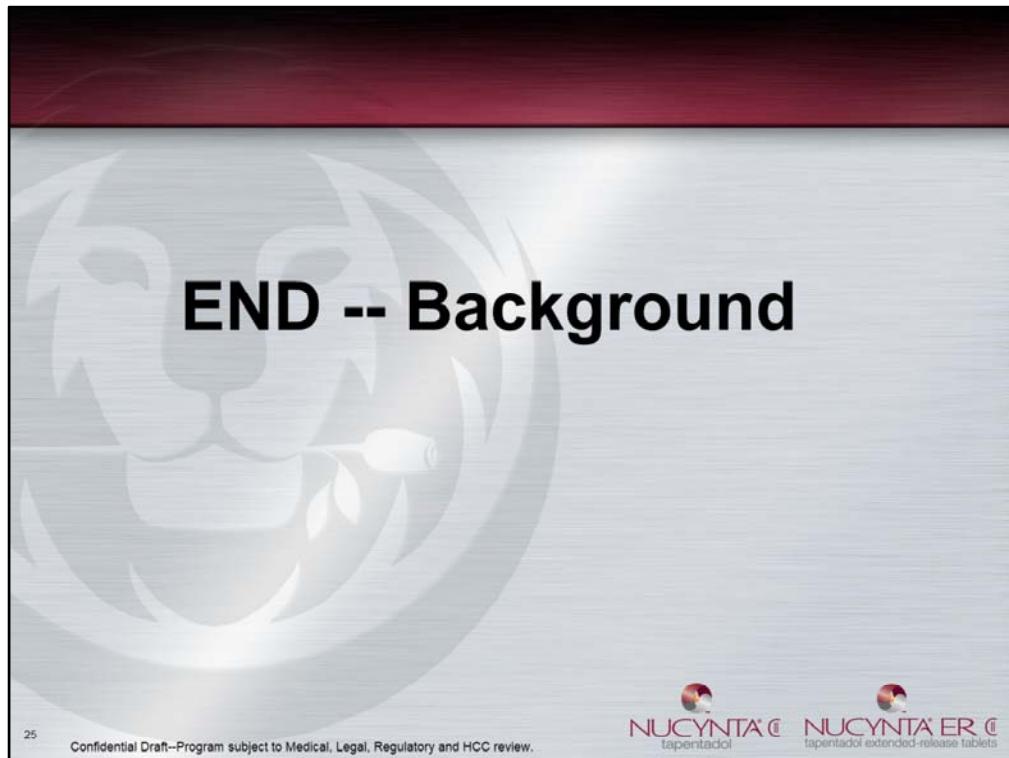
### Teen prescription drug abuse summit

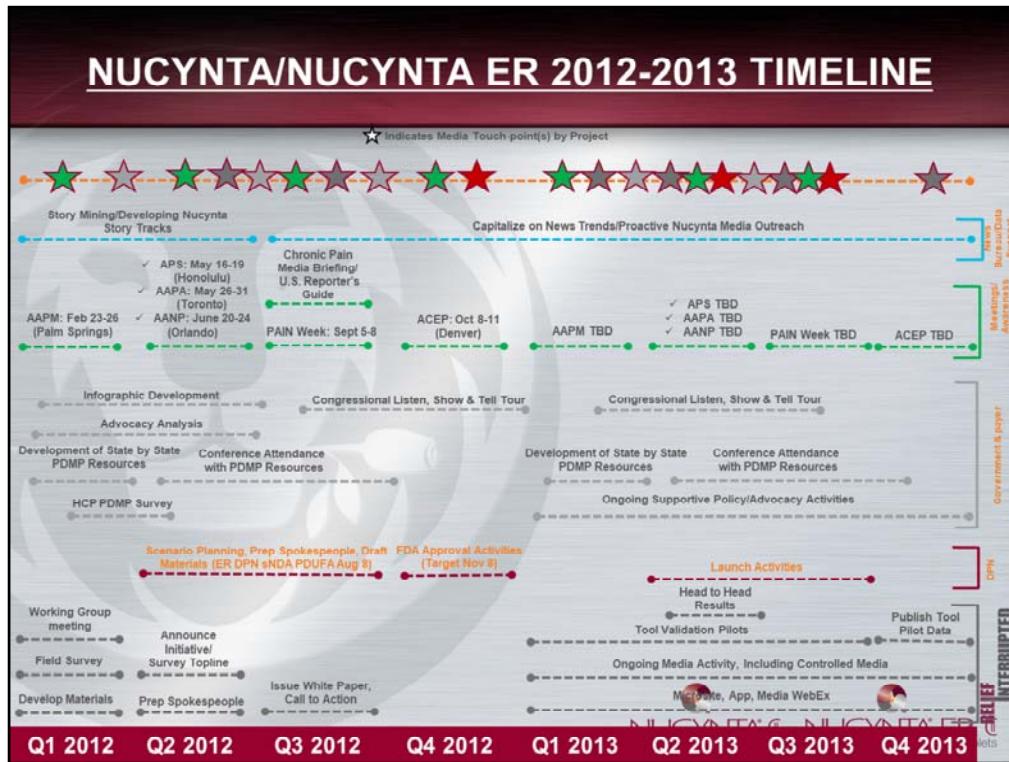
Potential partner and venue: Natl. Center on Addiction and Substance Abuse at Columbia University



H2H study data reporting timing to be added

Smart Moves program elements to be verified, moved to appropriate timing areas





Seizing Short-term Media Opportunities for NUCYNTA® / NUCYNTA® ER						
Month	Audience	Pitch	Targets	News Hook	Brand Track	
February	Consumer	Women & Pain—"Women are feeling the pain, study says—what every woman needs to know"	National & local radio, local market TV, women's books, consumer online	Journal of Pain-Gender Difference Study	What is tolerability and why does it matter? What are the differences in newer pain treatments?	
	Professional	Reporter briefings on NUCYNTA® data @ AAPM	Medical trades reaching pain specialists, PCPs, NPs, P.A.s, Ob/gyns, orthopedic surgeons, D.O.'s, pharmacists	AAPM	Data	
March	Consumer	"The long road home"—Iraq/Afghanistan troops the next gen of chronic pain patients	American Legion, Radio/print/TV in Ohio, Florida, California (large military & retired military pop)	Major troop withdrawals begin, large numbers of active duty returning to civilian life, tie vet struggle to everyman pain	Why is tolerability important in managing chronic pain? A newer treatment exist to help	
	Professional	Veterans—tools for dealing with chronic pain	Medical trades reaching PCPs, pain specialists, neurologists, orthopedic surgeons, pain specialists, general surgeons, rehab MDs	Those who have served, need to be served	Why is tolerability important in managing chronic pain? A newer treatment exist to help	

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Seizing Short-term Media Opportunities for NUCYNTA® / NUCYNTA® ER						
Month	Audience	Pitch	Targets	News Hook	Brand Track	
April	Consumer	When Work Hurts: Occupation/workplace pain: public servants, construction, athletes, skilled labor	National & local radio, local market TV, workplace segments, HR trades	Pitches tailored to workforce priority markets: focusing on repetitive stress injuries and accidents on the job—chronic pain mgmt, big economic impact on families, work	Importance of tolerability Pain management, new medication can help rehabilitation New medication, more choice	
	Professional		Family practice, pain, hospital trades, nursing trades			
May	Consumer	Bouncing back from pain: For the elderly, getting up and moving after surgery or an injury is vital to recovery—making a difference in health and longevity. Pain can be a barrier to bouncing back.	Weekend morning shows, retirement markets in priority states, retirement community pubs, senior pubs, radio, caregiver columnists, online, nursing trades	Data supports the need to be ambulatory after surgery or for many degenerative conditions. Ineffective pain management can contribute to the decline of a patient's health by limiting mobility	Why is tolerability important and how can it help/impede the recovery process? New medicine can help certain populations with pain	
	Professional	NUCYNTA® IR/ER data, or leverage opportunity off of category data	Pain trades, local market media around meeting	APS	NUCYNTA® IR/ER brand messages, data messages	 

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**Seizing Short-term Media Opportunities  
for NUCYNTA® / NUCYNTA® ER**

Month	Audience	Pitch	Targets	News Hook	Brand Track
June	Consumer	Relief interrupted patient survey shows impact of discontinuation on pain management and potential for abuse and diversion	Broad consumer outreach—television, radio, consumer books	Potential source of abuse and diversion —new survey shows	NUCYNTA® / NUCYNTA® ER approved messages on efficacy, tolerability
	Professional	Relief interrupted patient survey shows impact of discontinuation on pain management and potential for abuse and diversion	Pain trades, HCP trades	Potential source of abuse and diversion —new survey shows ...how physicians can help solve the problem	NUCYNTA® IR/ER approved messages on efficacy, tolerability

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## AAPM Media Approach

### Scenario 1:

- Press release in support of PAI-3025 poster: Efficacy and tolerability of Tapentadol IR versus Oxycodone IR for Moderate to Severe, Acute Low Back Pain with Radicular Leg Pain
- Media Targets: Medical trade media reaching pain specialists, PCPs, NPs, Phys Assts, Pharmacists, Ob/gyns
- Consider select consumer health media

### Scenario 2:

- Press release in support of PAI-3025 poster: Efficacy and tolerability of Tapentadol IR versus Oxycodone IR for Moderate to Severe, Acute Low Back Pain with Radicular Leg Pain
- **Pitch mention of RADARS data** on Tapentadol abuse, non-use among college students
- Media Targets: Medical trade media reaching pain specialists, PCPs, NPs, Phys Assts, Pharmacists, Ob/gyns

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## AAPM Message Track

- At this year's American Academy of Pain Management (AAPM) meeting, data was shared comparing tapentadol (NUCYNTA®) versus oxycodone IR for moderate to severe, acute low back pain with radicular leg pain (sciatica).
- Results showed that a flexible-dosing regimen of tapentadol IR was non-inferior to oxycodone IR for relief of acute LBP, with a more favorable gastrointestinal tolerability profile.
- In addition, two RADARS System surveillance data also shared at AAPM showed that NUCYNTA® has low rates of abuse, misuse and diversion. In fact, one study showed that among college students, the rate is low and decreasing over time.
- Given the high unmet need for relief among pain patients, doctors can feel confident about NUCYNTA® and NUCYNTA® ER as an effective and tolerable alternative with a favorable discontinuation rate.

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## Bringing Relief Interrupted to Life Sooner: Advancing a Critical Data Point

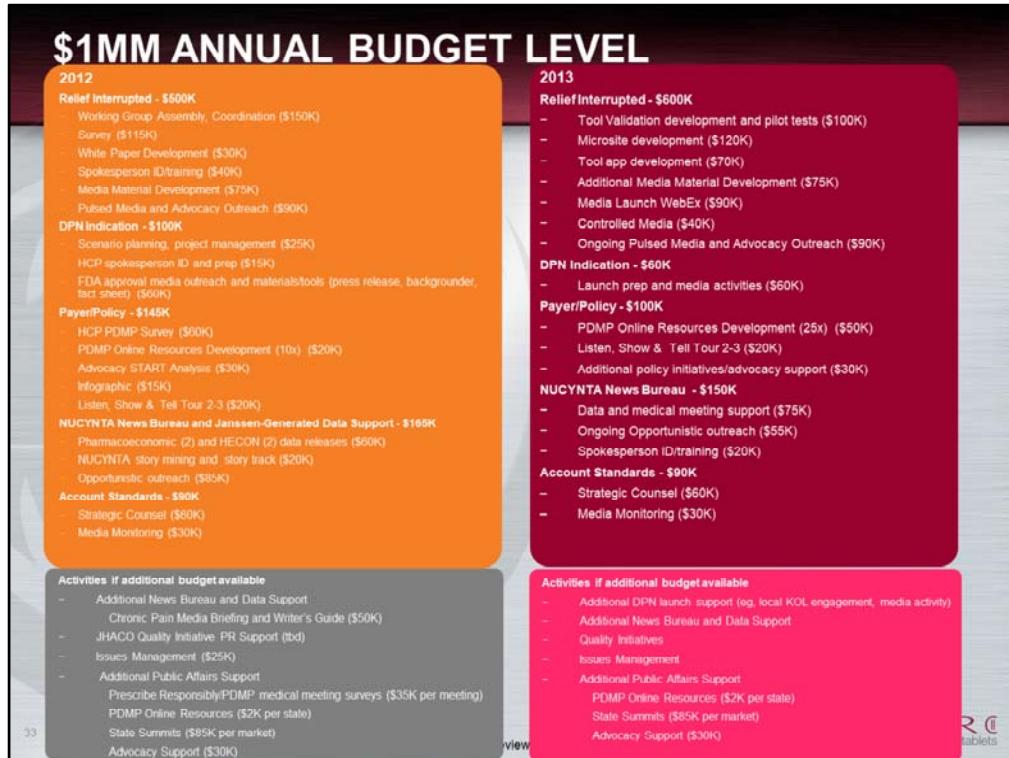
- “Fast track” consumer survey to help drive media interest, identify tolerability as a major culprit in discontinuation
  - When in their course of treatment do they discontinue?
  - What they do for pain management when they go off therapy?
  - Do they discuss other options with their doctors?
  - How many unused pills remain in the medicine cabinet?
- Merchandise survey data through media, advocacy groups, PDMP activities
  - Underscores need to re-evaluate treatment options to ensure patients are getting the relief they need

***Goal: Illustrating a need in the market and positioning  
NUCYNTA® / NUCYNTA® ER as the right solution for  
physicians by reinforcing what makes it different—  
efficacy and tolerability***

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## Clinical Data PR Support in 2010-2011 NUCYNTA® and NUCYNTA® ER (cont.)

### Press release on Wide Undertreatment of Acute Pain

#### • P3: Physicians Partnering Against Pain Survey

- 44% of U.S. patients in outpatient settings reported potentially inadequate relief of moderate-to-severe acute pain
- Older patients more likely to experience inadequate pain relief ( $p=0.0001$ )
  - Under 65      43%
  - 65-74          46%
  - 75 and older    52%
- 50,869 patients surveyed Sept to Nov 2008
- Janssen Scientific Affairs funded the survey

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### 1-Year Safety Study

Constipation (tapentadol ER, 22.6 percent; oxycodone CR, 38.6 percent); Nausea (tapentadol ER, 18.1 percent; oxycodone CR, 33.2 percent); and Vomiting (tapentadol ER, 7.0 percent; oxycodone CR, 13.5 percent).

## Sample Quotes from Media Coverage

**Extended-Release Opioid Gets FDA Ok**  
August 26, 2011

"Chronic pain is difficult to manage, and even with the treatments available today, it can be a challenge to balance pain relief with a patient's ability to tolerate the medicine," Sunil Panchal, MD, president of National Institute of Pain, said in a press release from Janssen. "People with chronic pain will continue to need additional options, so an approval like this is welcome news..."

**J&J Wins Nucynta ER Approval, Targets Chronic Pain Market**  
August 26, 2011

"We will be able to provide doctors with options now for treating different kinds of pain," said Paul Chang, VP of internal medicine and medical affairs at Janssen Pharmaceuticals, a division of J&J...  
  
J&J already has plans in the works to educate both doctors and consumers about the proper use of opioids. The Big Pharma has been adding content to [www.PrescribeResponsibly.com](http://www.PrescribeResponsibly.com) and to [www.LetsTalkPain.com](http://www.LetsTalkPain.com) to help its target audience better understand how the drug should be used. "While we have offered therapies for pain management for many years, we think it is extremely important to provide education around the use of these products," said Chang.



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## Research About *Let's Talk Pain* Web Site

- July/Aug 2011: Online survey--758 members of APF
- Asked to review [www.LetsTalkPain.org](http://www.LetsTalkPain.org) before completing
- Key takeaways...
  - Asked to consider the 6 **current site features**, respondents asked to choose the one they would find most useful
    - Info on treatment options, such as non-opioid & futures 82 percent
    - Tools for communicating about pain (videos, pain journal) 73 percent
  - 35.8% provided additional suggestions for site (unaided)
    - Tips for creating and utilizing support groups
    - Online forum or message board
    - Caregiver education
    - Tips for coping with emotional issues
    - Updated info on alternative therapies
    - Medical news and current events in the pain arena
    - Skills for communicating with pharmacists

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## Opportunities for *Let's Talk Pain*

- Develop communication tools for patients/HCPs to launch with findings on gaps found in surveys
- Consider adding LTP members to strengthen coalition
  - Dispell misunderstanding about advocacy organizations
- Tell the true story of unmet medical need in chronic pain patients

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## SMSC in 2008-09

- **2008: Produced 5 videos with “The NewsHour”**
  - <http://www.pbs.org/newshour/thenews/themedic/>
- **2009: Dr. Drew Pinsky**
  - 3 school assemblies
  - TV satellite media tour



38 Confidential Draft--Program subject to Medical, Legal, Regulatory and HCC review.

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